

**Notice of Allowability**

Application No.

09/978,599

Applicant(s)

ABOVITZ ET AL.

Examiner

Jacqueline Cheng

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/30/06.
2. ☒ The allowed claim(s) is/are 2-15, 17-32, 34-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Please replace the abstract as follows in order for it to meet the requirement of being generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words:

A software-integrated disposable kit contains a series of sterile packages which hold instrumented surgical tools, surgical accessories, user input computer controlling peripherals (e.g. mouse, keyboard), markers, and a one time use digital medium. When image guided surgery is to be performed, the digital medium is inserted into the computer and the user interface is displayed. The digital medium stores a portion of the software which, in combination with software on the computer, provides all of the software necessary for full user functionality (e.g. display diagnostic image information, tracking surgical instruments, superimposition of surgical tools). At the end of a surgical procedure, the digital medium is deactivated or encrypted and the used surgical tools are then disposed of without reuse. The system allows the user to save relevant information obtained from the surgery (e.g. images, notes) on the digital medium which is encrypted against reuse and archived.

### REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: The applicant's arguments filed in the appeal brief have been persuasive. Upon further search general art on image guided surgery systems which can accept sterile surgical tools for preselected surgical procedures and can track the tools are well known in the art such as disclosed by US 6,331,181 B1 to Tierney. It is also well known in the art to install application specific software to a system to facilitate performance of the surgical tool used in the preselected surgical procedure as disclosed by both US 6,331,181 to Tierney (col. 2 line 47-54 wherein the system can reconfigure it's programming to have application specific software) and US 2001/0034530 A1 to Malackowski (paragraph 0006 wherein it is well known that additional software is often required to be installed for new instruments). What is not well known in the art is to the particulars of what is claimed wherein the system only has a portion of the image guided surgery software, providing minimal user functionality, and a kit comprising both instrumented surgical tools for a preselected surgical procedure, and a disposable, one time use, digital medium for updating the system with the application specific software specific to the preselected surgical procedure.

### CONCLUSION

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

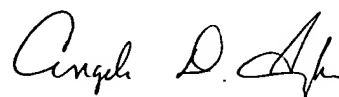
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596.

The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC



**ANGELA D. SYKES**  
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